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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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BUGAISKY, GABRIELE E

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1653

DATE MAILED: 09/10/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------|----------------|
| Office Action Summary | Application N . | Applicant(s) |
| | 09/493,795 | WATKINS ET AL. |
| | Examiner | Art Unit |
| | Gabriele E. BUGAISKY | 1653 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 13 June 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) 3-7 and 10-38 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,8, 9 is/are rejected.

7) Claim(s) 39 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5, 8</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, SEQNID Nos 5 and 236 in Paper No. 14 is acknowledged. The traversal is on the ground(s) that

a particular class of conotoxins will share a conserved cysteine framework, disulfide bridging pattern and conserved molecular target. and that there is no serious search burden. . .
This is not found persuasive because while it is agreed that that the α - conotoxins share a general 3 dimensional structure and share a similar cysteine framework and disulfide bridging pattern, there indeed is a serious search burden. Applicant state that the individually required search for each sequence is only a result of the limitations in the programming of the search engines and that nothing prevents one skilled in the art from writing a program that would search the peptide chemical genus as presently exists for more the traditional chemical genus. The Examiner is of necessity limited to the search tools at hand. At present, the Examiner searched the general formula of SEQ ID NO:1 for the cysteine framework (with all 13 variable amino acids present) and the specific peptide chosen for search purposes, in addition to a detailed word search of published references , including issued patents. Thus, what was searched for SEQ ID NO:1 was the generic formula XXXXXCCXXXXCXXXCX, wherein no X was defined. The Examiner had to then analyze the search results to determine whether the over 250 100% matching sequences contained any of the recited variables at each X position. For search purposes, the Examiner does however, consider , e.g., a modified Tyr such as those recited in claim 1, line 18, to be the same as Tyr. At present, it is impossible to search for all the variables recited at any of 13 Xaa positions of general formula I; it should be pointed out that the primary structure of 6

cysteines and 13 other amino acids is not even general as at least 5 of the variable amino acids may be missing, thus yielding a peptide with 5 cysteines and 8 other amino acids. This situation constitutes AT PRESENT a serious search burden. The Examiner cannot speculate when and if a search program may ever become available that would function as Applicants state is possible; the Examiner can only operate with the search tools currently available to her. The requirement is still deemed proper and is therefore made FINAL.

Claims 3-7 and 10-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 14.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The listing of references in the specification (pages 67-68) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore,

unless the references have been cited by the examiner on form PTO-892 or by Applicants on form PTO-1449, they have not been considered.

Specification

The disclosure is objected to because of the following informalities: the specification has blanks for the serial numbers of several applications, e.g., page 2, lines 10 and 12, page 23, lines 16-17.

Appropriate correction is required.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Applicants are required under 37 C.F.R. 1.821-1.825 to amend their claims to specific sequences by citing the appropriate SEQ ID Nos.

Claim Objections

Claims 2 and 39 are objected to because of the following informalities:

Both claims recite non-elected subject matter .

Claim 39 currently recites sequences contained in Tables, rather than SEQ ID NO:

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The final line of claim 2 recites “. . . or derivatives thereof.” It is unclear whether the claimed derivatives are those of SEQ ID NOS 5-12 or to those at the C-terminus; if the latter is intended then are those solely of the amide group, the carboxyl group or either. Claim 9 is included in this rejection as it depends from claim 2 and does not clarify the ambiguity.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Olivera *et al.*(5514774) The reference provides the α -conotoxin U002 of SEQ ID NO:12 (GCCSDPRCAWAC), which fits the formula of SEQ ID NO:1, wherein Xaa1 is des, .Xaa2 is des, Xaa3 is des, Xaa4 is des, Xaa5 is Gly, Xaa6 is Ser, Xaa7 is Asp, Xaa8 is Pro, Xaa9 is Arg, Xaa10 is Ala, Xaa11 is Trp, Xaa12 is Arg and Xaa13 is des. A species anticipates a genus. With respect to claim 8, the specification teaches (column 6, lines 1-25) that conotoxins with post-translational modifications (including glycosylation of Ser and/or Thr residues) are within the scope of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5514774. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to the specific species of U002 (SEQ ID NO:12).

Conclusion

Claims directed to the conotoxin of SEQ ID NO:5 and its precursor SEQ ID NO:236 are deemed to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gabriele E. BUGAISKY whose telephone number is (703)308-4201. The examiner can normally be reached on 8:15-12:15 M, 8:15-1:15 Tu-F.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher SF Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703 308-4242 for regular communications and 703 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 708 308-0196.



geb
September 6, 2002

Gabriele E. BUGAISKY
Primary Examiner
Art Unit 1653

**GABRIELLE BUGAISKY
PRIMARY EXAMINER**